PATENT
Attorney Docket No. ETH5110USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:	)	) Confirmation No.: 6984
Frank Richard Cichocki, Jr.	)	Group Art Unit: 3731
Serial No. 10/727,367	)	Examiner: Lang, Amy T.
Filed: December 4, 2003	)	
For : ACTIVE SUTURE FOR THE DELIVERY OF THERAPEUTIC FLUIDS	)	

United States Patent and Trademark Office
401 Dulany Street
Alexandria, VA 22314

APPEAL BRIEF

As set forth in the notice of appeal filed October 17, 2008, Appellant hereby appeals the Examiner's final rejection of claims 1, 2, 4 and 6 of the above-identified application, with claims 3, 5 and 7-23 being withdrawn from consideration. Appellant respectfully requests that the Board of Patent Appeals and Interferences ("Board") reverse the final rejection of these claims.

I. REAL PARTY IN INTEREST

ETHICON INC is the real party in interest.

II. RELATED CASES

This case is related to pending U.S. Patent Application Serial No. 10/909,717. There are no related appeals or interferences.

III. JURISDICTIONAL STATEMENT

The Board has jurisdiction under 35 U.S.C. § 134(a). The Examiner mailed a final rejection on July 18, 2008, setting a three-month shortened statutory period for response. The time for responding to the final rejection expired on October 18, 2008. Rule 134. A notice of appeal was timely filed on October 17, 2008. The time for filing an appeal brief is two months after the filing of a notice of appeal. Bd.R.41.37(c). The time for filing an appeal brief expired on December 17, 2008. An amendment was filed on December 17, 2008. An advisory action was mailed January 12, 2009 entering the December 17, 2008 amendment for purposes of appeal. The appeal brief is being filed on February 12, 2009 with a two month extension of time.

IV. TABLE OF CONTENTS

V. TABLE OF AUTHORITIES

Cases

VI. STATUS OF AMENDMENTS

An amendment was filed after final rejection on December 17, 2008. An Advisory Action was mailed on January 12, 2009 entering the amendment filed on December 17, 2008 for purposes of appeal.

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant respectfully requests the Board to reverse the following grounds of rejection:

(1) Rejection of claims 1, 4 and 6 under 35 U.S.C. § 102(b) as being anticipated by Burton (U.S. Patent No. 4,159,720).

(2) Rejection of claim 2 under 35 U.S.C. § 103(a) as being unpatentable over (1) Burton (U.S. Patent No. 4,159,720) in view of (2) Davis et al. (U.S. Patent No. 3,474,703).

VIII. STATEMENT OF FACTS

(1) In rejecting claims 1, 4 and 6, the examiner, at page 2 of the final office action mailed July 18, 2008, cites Burton (i) FIG. 14, (ii) col. 4, lines 46-49, (iii) col. 2, lines 13-18, and (iv) col. 5, lines 6-8, which are reproduced below:

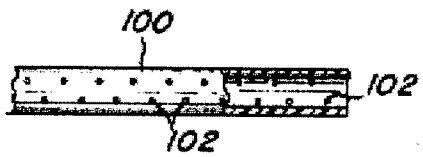


Fig. 14

(i)

As shown in FIG. 14 the wick may have the form of a hollow monofilament 100 of fore example nylon, provided with lateral perforations 102 through which the fluid will pass into the tissue. As shown in FIG. 15 the wick may also have the form of a solid filament 104 having spiral grooves 106 in its external surface. As shown in FIG. 16 the filament 104 may have longitudinal groove 108. (ii)

The wicks can be strands of any conventional form that will absorb or convey by capillary action an appreciable quantity of the fluid to be used for the treatment of the tissue. The wick means can be selected to deliver a known rate of the prescribed fluid into the flesh in which the wick has been installed. (iii)

reservoirs 10 and 24. The ends of the wicks absorb the fluid that is gradually fed along the length of the wick by absorption or capillary action. When the wick has (iv)

(2) The examiner, at page 2 of the final office action mailed July 18, 2008 asserts that:

With regard to **claim 1**, Burton discloses a braided suture having proximal and distal ends (see entire document). As shown in Figure 14, the suture comprises a hollow inner passageway coaxial with the braided suture (column 4, lines 46-49). A

(3) Burton FIG. 14, col. 4, lines 46-49, as shown above, only discloses an alternative embodiment of the "wick" 48 of Burton and that the wick "may have the form of a hollow monofilament 100" with "lateral perforations 102 through which the fluid will pass into the tissue."

(4) Burton FIG. 14, col. 4, lines 46-49, does not disclose "a hollow inner passageway coaxial with a braided suture."

(5) The examiner, at page 2 of the final office action mailed July 18, 2008 correctly admits that Burton does not disclose a passageway disposed between proximal and distal ends of a braided suture:

However, Burton does not specifically disclose wherein the distal end of the passageway is disposed between the proximal and distal ends of the braided suture. If

(6) The examiner, at page 3 of the final office action mailed July 18, 2008 incorrectly characterizes Burton as disclosing that suture material must be present at a distal end to take in fluid:

the suture absorb the fluid (column 5, lines 6-8). Therefore, since the fluid is absorbed, suture material must be present at the distal end to take in the fluid.

(7) In Burton, the ends of the "hollow monofilament 100" can absorb a fluid by "capillary action," as disclosed at col. 5, lines 6-8 of Burton.

(8) In rejecting claim 2, the examiner, at page 4 of the final office action mailed July 18, 2008, cites (i) Burton col. 4, lines 21-45, and Davis et al. (ii) col. 1, lines 14-22, (iii) col. 3, lines 25-45, and (iv) col. 3, lines 68-74, which are reproduced below:

(i)

The wicks themselves preferably take the form of an elongated flexible suture-like material **48**, as best shown in FIGS. **6**, **8** and **12**, adapted to be installed in the subcutaneous flesh with any conventional form of curved cutting or tapered suture needle. The wick shown in FIG. **6** was led into its installed position as if it were a suture and indeed in one use to which the invention may be put, the wick serves as a suture for holding the severed flesh together as well as a carrier or conduit for delivering fluid antibiotic or anesthetic substances and the like, directly to the affected area.

The wicks may be made of an absorbent suture material such as silk or cotton that is braided, woven or otherwise formed of a length to reach from the reservoir into the tissue to be treated or as shown in FIG. **12**, from one reservoir, through the tissue and out of the body, to be connected to a second reservoir. The woven wick can be formed to a tubular or other cross-sectional shape, whichever shape and tightness of weave serves to best absorb or wet the wick to carry the fluid by capillary action along the length of the wick from the reservoir into contact with the tissue. The suture material may be further twisted or woven to include a copper thread for electrophoresis to increase wick flow by attaching the suture into an electrical battery system.

(ii)

A capillary device that is rigid and, at the same time, is capable of providing for the flow of liquids in both axial and radial directions is prepared by bonding the filaments of a braided structure together at the points of intersection of the filaments of the braid. These devices are particularly useful, for example, in applications wherein the capillary devices serve both to feed a fluid and to distribute fluid over a surface such as is the case with pen points, wick lubricators, and the like.

(iii)

FIG. 2 illustrates the construction of the device of FIG. 1 in which the braided device **1** is comprised of an outer braid **2** braided around an inner braid **3**.

It is thought that when adjacent filaments of the braid are properly bonded together in accordance with the teachings of this invention, the bonding occurs primarily at the intersection of these filaments where essentially point contact is made. It is believed that this prevents the capillary spaces from becoming blinded and thus the flow of fluids through the capillary device is not restricted in either an axial or radial direction.

In preparing capillary devices in accordance with this invention, it may be found useful to use a plurality of concentric braids. By this means, small diameter filaments may be utilized to provide a small diameter braid, and by braiding concentric layers over the initial braided structure, a capillary device of the desired diameter can be built up.

Sometimes it may be desirable to provide a small central passageway in the interior of the innermost braid. While

(iv)

braid. It can be appreciated that the larger the diameter, the larger will be the open areas between the various filaments of the braid and, accordingly, the greater will be the rate of flow. Also, some control over the open areas can be obtained by using filaments having differing diameters or filaments having non-circular cross sections (multi-lobal). In both cases, the geometry of the cross sec-

(9) The examiner, at page 4 of the final office action mailed July 18, 2008 correctly admits that Burton does not disclose a suture comprising a tube within an inner lumen:

action to move liquid along its length (Column 4, lines 21-45). However, Burton does not specifically disclose the suture as comprising a tube within the inner lumen.

(10) The examiner, at page 4 of the final office action mailed July 18, 2008 correctly admits that Davis et al. does not disclose a ratio of an outer diameter of an inner tube to an inner diameter of a tube:

Although Davis does not specifically disclose the ratio of the outer diameter of the inner tube to the inner diameter of the tube, it would have been obvious to one of

(11) The examiner, at page 4 of the final office action mailed July 18, 2008 incorrectly characterizes Davis et al. as disclosing utilizing "a hollow inner tube":

lines 25-45). Davis teaches the flow of fluids is not restricted in either an axial or radial direction when utilizing a hollow inner tube (column 3, lines 35-36). Therefore, in view

(12) Davis et al. at col. 3, lines 44-45 discloses utilizing a central passageway in an innermost braid and not "a hollow inner tube."

(13) The examiner, at page 2 of the advisory action mailed January 12, 2009 incorrectly characterizes Burton as inherently disclosing suture material being present in the passageway of Burton:

> Burton specifically teaches that the ends of the passageway absorb the fluid through capillary action so that suture material is inherently present. The capillary action absorbs the fluid into the openings of the suture material. Furthermore, although capillary action is possible without suture material at the ends of the passageway to draw the fluid in the passageway, it would not be possible to specifically absorb the fluid without suture material present.

(14) The examiner, at page 2 of the advisory action mailed January 12, 2009 incorrectly characterizes Appellant's specification as failing to show the claimed ratio was obtained through experimentation:

> Applicant also argues that the ratio of diameters of the inner braid to the outer braid is not obvious. However, the instant specification only recites this ratio as preferable and does not provide evidence to show it as obtained through experimentation and not obvious.

(15) Appellant's specification at pages 21, lines 10 to page 22, line 2 shows that the claimed ratio was obtained through experimentation:

> Example 3
> Experimental data indicates that extruded polymeric tubes produced from polypropylene, with outside diameters ranging from .005" to .010", with Youngs Moduli ranging between 0.1 and 3 GPa, with outside diameters (O.D.s) that are less than 1.7 times that of their inside diameters (I.D.s) will buckle and collapse when the braided sutures in which they are embedded are tied into square knots similar in form to those commonly used in surgical procedures. Similar experiments conducted with polymeric tubes comprised of polyethylene and polytetraflouroethylene with Youngs moduli ranging between 0.1 and 3 GPa with O.D. to I.D. ratios of greater than 2.3 do not collapse completely inside the square knots of the active suture and fluid can indeed be transferred through the knotted portions. For active sutures that will be tied into knots, preferably the ratio of the O.D. to I.D. is greater than 1.7. More preferably, the ratio of the O.D. to I.D. is greater than 2.0. In these experiments, the tubes were embedded in braided sutures produced from polyethyleneterephthalate (PET) fibers with USP sizes ranging from 2-0 to 5. Other variables that influence the likelihood of collapse of the lumen inside of knots include thickness of the braided suture in which the internal passageway is imbedded, strength of the fluid conducting tube, and the overall tension applied in forming the knots.

IX. ARGUMENT

The rejection of claims 1, 4 and 6 under 35 U.S.C. § 102(b), as being anticipated by Burton (U.S. Patent No. 4,159,720), should be REVERSED.

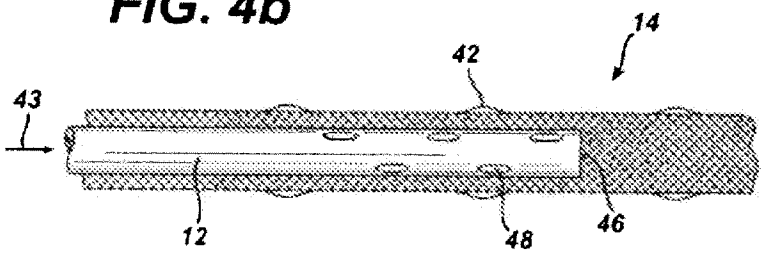
With respect to this rejection, claims 1, 4 and 6 stand or fall together. Independent claim 1 and claims dependent therefrom are allowable over Burton, because Burton fails to anticipate the invention recited in the claims, which have been rejected on the basis thereof, for the following reasons.

Burton proposes a means for delivering a prescribed liquid medicine or other fluid to a subcutaneous tissue. The device includes a reservoir on the outside of the body for holding a supply of the prescribed liquid, the reservoir being adhesively attached to the skin near the tissue to be treated. The reservoir feeds the liquid to absorbent or capillary wicks adapted to pass through the skin to be installed in the subcutaneous tissue to which the fluid is to be fed. The wicks may be provided in several forms such as twisted or braided suture material, the ends of which, in some instances, may be encased in plastic. The wicks, in whatever form, are guided from the outside into their installed positions in the subcutaneous tissue with conventional cutting or tapered surgical needles, and in the modification making use of a plastic casing, a slightly modified needle is used to install the wick cover (see, e.g., Abstract and FIG. 6 of Burton).

By contrast, the invention of independent claim 1, as shown in FIG. 4b below, includes in relevant part at least one passageway [12] coaxial with at

least a portion of a braided suture [14], and having proximal and distal ends and a diameter that is less than a outer diameter of the braided suture and having one or more openings [48] therein so that the at least one passageway conducts fluid to the plurality of interstices of the braided suture and a distal end [46] of the at least one passageway is disposed between proximal and distal ends of the braided suture.

FIG. 4b



In addition, the invention of independent claim 1 includes the recognition of problems discovered by Appellant of merely relying on capillary action with the prior art device of Burton (see, e.g., page 5, line 16 to page 6, line 4 of Appellant's specification) and advantageously provides a high level of drug delivery rate control and enables a physician to start or stop drug administration at his/her discretion, as compared thereto (see, e.g., page 6, line 5 to page 7, line 3 of Appellant's specification).

By contrast, as shown in FIGs. 6, 9 and 14, reproduced below, and discussion thereof, as previously argued by Appellant at page 16 of the response filed on December 17, 2008, Burton merely discloses a wick [48] that can be a

hollow monofilament [100] with lateral perforations [102] (see, e.g., col. 4, lines 46-49 of Burton) and with an enlarged end [56].

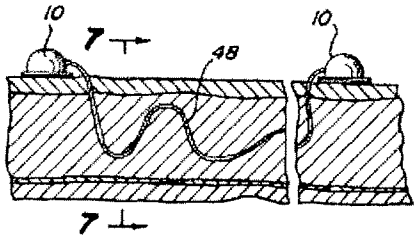


Fig. 6

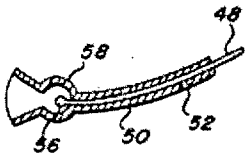


Fig. 9

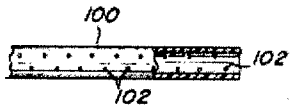


Fig. 14

Accordingly, contrary to the assertions by the examiner at pages 2-3 of the final office action mailed July 18, 2008 and at page 2 in the advisory action mailed January 12, 2009, the noted features or advantages of at least independent claim 1 are not disclosed, taught or suggested by Burton.

Thus, as previously argued by Appellant at page 16 of the response filed on December 17, 2008, Burton merely discloses that the wick [48] of Burton can be a hollow monofilament [100]. As such, Burton proposes a braided suture [48], and a connector [58]; **or, alternatively**, a hollow monofilament [100], and a connector [58]. Nowhere does Burton describe the use of both the braided suture and the hollow monofilament **in the same assembly**. Accordingly, the examiner correctly admits at page 4 of final office action mailed July 18, 2008 that "Burton

does not specifically disclose the suture as comprising a tube within the inner lumen."

Moreover, in the final office action at page 3 and the advisory action at page 2 the examiner incorrectly characterize Burton as disclosing that suture material must be present or is inherent at a distal end to take in fluid. Specifically, as previously argued by Appellant at pages 16-17 of the response filed on December 17, 2008, in Burton, the ends of the "hollow monofilament 100" can absorb a fluid by "capillary action," as disclosed at col. 5, lines 6-8 of Burton, so that, contrary to the assertion in the final office action and the advisory action, suture material need not be present.

Thus, the noted features or advantages of independent claim 1 are not disclosed, taught or suggested by Burton. In addition, there would be no motivation to modify Burton to arrive at the invention of independent claim 1, absent improper hindsight reconstruction of the invention, based on Appellant's invention disclosure.

As stated in M.P.E.P. §2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Burton clearly fails to teach each and every element of Appellant's invention, as presently claimed in claim 1, either expressly or inherently. Nowhere does Burton disclose an active

suture that includes a tube having an internal passageway for conducting fluid to a plurality of interstices of a braided suture.

Accordingly, it is respectfully requested that the Examiner's rejection of claims 1, 4 and 6 under 35 U.S.C. §102(b) as being anticipated by Burton be reversed.

The rejection of claim 2 under 35 U.S.C. § 103(a), as being unpatentable over Burton (U.S. Patent No. 4,159,720) in view of Davis et al. (U.S. Patent No. 3,474,703), should be REVERSED.

With respect to this rejection, independent claim 2 is allowable over Burton and Davis et al., because Burton and Davis et al., alone or in combination, fail to render obvious the invention recited in claim 2, which has been rejected on the basis thereof, for the following reasons.

Davis et al. fails to cure the noted deficiencies in Burton, and as shown in FIG. 2 and discussion thereof, Davis et al. merely discloses a braided capillary device that includes an outer braid 2, braided around an inner braid 3, which can have a small central passage way formed therein (see, e.g., col. 3, lines 26-56 of Davis et al).

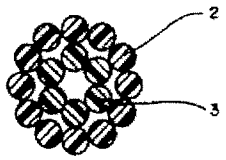
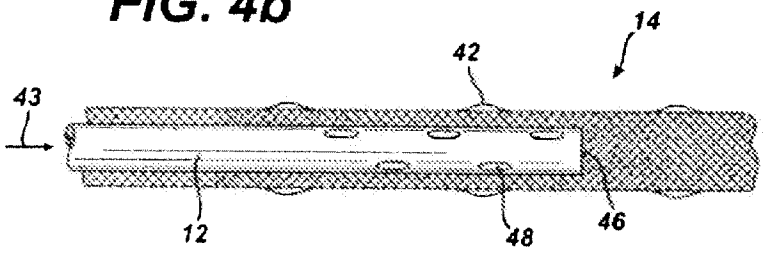


FIG. 2

Accordingly, contrary to the assertion by the examiner at page 4 of the final office action mailed July 18, 2008, Davis does not disclose a hollow inner tube. In addition, as previously argued by Appellant at page 17 of the response filed on December 17, 2008, Davis et al. is silent with respect to the relationship or advantages of the ratio of the diameters of the outer braid 2 and the inner braid 3, and which according to the present invention is not a mere design choice, as asserted by the examiner at pages 4-5 of the final office action mailed July 18, 2008, but rather provides the noted advantages of independent claim 2. Moreover, contrary to the assertion by the examiner at page 2 of the advisory action mailed January 9, 2009, the claimed ratio was arrived through experimentation to provide the noted advantages of independent claim 2, and as previously argued by Appellant at page 15 of the response filed on December 17, 2008.

By contrast, the invention of independent claim 2, as shown in FIG. 4b below, includes in relevant part a tube [12] coaxial with at least a portion of a braided suture [14], having an outer diameter that is less than an outer diameter of the braided suture and an inner diameter, and having one or more openings [48] therein so that the tube conducts fluid to the plurality of interstices of the braided suture and the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7.

FIG. 4b



Advantageously, and based on experimental results, for active sutures that will be tied into surgically acceptable knots such as square knots or surgeons knots, preferably the ratio of the tube outside diameter (O.D.) to inside diameter (I.D.) is greater than 1.7, wherein experimental data indicates that extruded polymeric tubes produced from polypropylene, with outside diameters ranging from 0.005" to 0.010", with Youngs Moduli ranging between 0.1 and 3 GPa, with outside diameters (O.D.s) that are less than 1.7 times that of their inside diameters (I.D.s) will buckle and collapse when the braided sutures in which they are embedded are tied into square knots similar in form to those commonly used in surgical procedures (see, e.g., page 16, line 14 to page 17, line 3 and page 21, line 10 to page 22, line 2 of Appellant's specification).

In addition, as previously argued, the invention of independent claim 2 includes the recognition of the problems discovered by Appellant of merely relying on capillary action as with the prior art device of Burton and advantageously provides a high level of drug delivery rate control and enables a

physician to start or stop drug administration at his/her discretion, as compared thereto.

Thus, the noted features or advantages of independent claim 2 are not disclosed, taught or suggested by Burton and Davis et al., alone or in combination. In addition, there would be no motivation to modify Burton and/or Davis et al. to arrive at the invention of independent claim 2, absent improper hindsight reconstruction of the invention, based on Appellant's invention disclosure.

It is respectfully submitted that, as the Federal Circuit noted in In re Gordon, at 221 USPQ 1127, 733 F.2d 902, "the mere fact that the reference could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." It is respectfully submitted that the lack of technical motivation for making the modifications necessary to arrive at Appellant's claimed invention is evidence that the suggestion for the modification could not have come from the reference itself. In view thereof and the arguments above, the applicant respectfully requests that the rejection of claim 2 under 35 U.S.C. 103(a), as being unpatentable over Burton and Davis et al., be reversed.

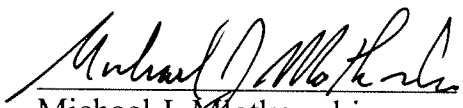
CONCLUSION

On the basis of the foregoing, all of the Examiner's rejections should be reversed and such action is hereby requested.

The brief fee set forth in 37 C.F.R. § 41. 20(b)(2) is authorized to be charged to the Deposit Account No. 50-2478 (13788) of the undersigned's firm in a separate paper that accompanies this Brief. However, should that paper be missing, this paragraph should be construed as containing such an authorization.

Respectfully submitted,

Date: February 12, 2009



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APPENDIX

Claims

1. (Previously presented) An active suture comprising

a braided suture having proximal and distal ends and an outer diameter, said braided suture having a plurality of interstices along at least a portion of its length; and

at least one passageway coaxial with at least a portion of the braided suture, and having proximal and distal ends and a diameter that is less than the outer diameter of the braided suture and having one or more openings therein so that said at least one passageway conducts fluid to said plurality of interstices of said braided suture;

wherein the distal end of the at least one passageway is disposed between the proximal and distal ends of the braided suture.

2. (Previously presented) An active suture comprising

a braided suture having an outer diameter said braided suture having a plurality of interstices along at least a portion of its length; and

a tube coaxial with at least a portion of the braided suture, having an outer diameter that is less than the outer diameter of the braided suture and an inner diameter, and having one or more openings therein so that said tube conducts fluid to said plurality of interstices of said braided suture;

wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7.

3. (Withdrawn) An active suture comprising a first braided suture having an outer diameter and having embedded therein a coated fiber tow or coated braided suture coaxial with at least a portion of the first braided suture, said coated fiber tow or coated braided suture having an outer diameter that is less than the outer diameter of the first braided suture, and said coated fiber tow or coated braided suture having one or more opening therein.

4. (Original) The active suture of claim 1, where the at least one passageway is a lumen of a tube.

5. (Withdrawn) The active suture of claim 1, where the at least one passageway is within a coated fiber tow or a coated braided suture.

6. (Original) The active suture of claim 4, where the tube has one or more holes that connect the lumen to the outer surface of the tube.

7. (Withdrawn) The active suture of claim 5, where the coated fiber tow or coated braided suture has one or more holes that connect the at least one passageway to the outer surface of the coated fiber tow or coated braided suture.

8. (Withdrawn) The active suture of claim 3, further comprising a connector located on the proximal end of the at least one passageway, on one end of the tube, or on one end of the coated fiber tow or braided suture, said

connector being capable of attachment directly to a hypodermic needle or indirectly to an intravenous delivery system or fluid pump.

9. (Withdrawn) The active suture of claim 1, 2 or 3 further comprising an inflatable reservoir on the proximal end of the at least one passageway, on one end of the tube, or on one end of the coated fiber tow or braided suture.

10. (Withdrawn) The active suture of claim 9, further comprising a connector proximal to the inflatable reservoir.

11. (Withdrawn) A method of closing a wound using a suture/needle assembly comprising a braided suture having proximal and distal ends, an outer diameter, at least one passageway coaxial with at least a portion of the braided suture, said passageway having proximal and distal ends and a diameter that is less than the outer diameter of the braided suture, wherein the distal end of the at least one passageway is disposed between the proximal and distal ends of the braided suture; a surgical needle attached to the distal end of the braided suture; and a connector attached to the proximal end of the at least one passageway, comprising the steps of:

connecting the connector on the proximal end of the at least one passageway directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the at least one passageway;

introducing the suture/needle assembly into tissue surrounding the wound such that the distal end of the at least one passageway is at or in the proximity of the wound; and

closing the wound with the braided suture.

12. (Withdrawn) A method of administering a fluid to a wound that has been closed using a braided suture having proximal and distal ends, an outer diameter, at least one passageway coaxial with at least a portion of the braided suture, said passageway having proximal and distal ends, an opening at the distal end and a diameter that is less than the outer diameter of the braided suture, wherein the distal end of the at least one passageway is disposed between the proximal and distal ends of the braided suture; and a connector attached to the proximal end of the at least one passageway; such that the distal end of the at least one passageway is at or in the proximity of the wound, comprising the steps of:

connecting the connector on the proximal end of the at least one passageway directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the at least one passageway; and

allowing the fluid to exit the opening at the distal end of the at least one passageway into at least a portion of the braided suture at or in the proximity of the wound.

13. (Withdrawn) A method of closing a wound and administering a fluid to a wound using a suture /needle assembly comprising a braided suture having proximal and distal ends, an outer diameter; at least one passageway coaxial with at least a portion of the braided suture, said passageway having proximal and distal ends, an opening at the distal end and a diameter that is less than the outer diameter of the braided suture, wherein the distal end of the at least one passageway is disposed between the proximal and distal ends of the braided suture; a surgical needle attached to the distal end of the braided suture; and a connector attached to the proximal end of the at least one passageway; comprising the steps of:

introducing the suture/needle assembly into tissue surrounding the wound such that the distal end of the at least one passageway is at or in the proximity of the wound;

closing the wound with the braided suture;

connecting the connector on the proximal end of the at least one passageway directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the at least one passageway; and

allowing the fluid to exit the opening at the distal end of the at least one passageway into at least a portion of the braided suture at or in the proximity of the wound.

14. (Withdrawn) A method of closing a wound and administering a fluid to a wound using a suture /needle assembly comprising a braided suture having proximal and distal ends, an outer diameter; at least one passageway coaxial with at least a portion of the braided suture, said passageway having proximal and distal ends, an opening at the distal end and a diameter that is less than the outer diameter of the braided suture, wherein the distal end of the at least one passageway is disposed between the proximal and distal ends of the braided suture; a surgical needle attached to the distal end of the braided suture; and a connector attached to the proximal end of the at least one passageway; comprising the steps of:

connecting the connector on the proximal end of the at least one passageway directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the at least one passageway;

allowing the fluid to exit the opening at the distal end of the at least one passageway into at least a portion of the braided suture;

introducing the suture/needle assembly into tissue surrounding the wound such that the distal end of the at least one passageway is at or in the proximity of the wound; and

closing the wound with the braided suture.

15. (Withdrawn) A method of closing a wound using a suture/needle assembly comprising a braided suture having proximal and distal ends and an outer diameter; a tube coaxial with at least a portion of the braided suture, said tube having proximal and distal ends, an outer diameter that is less than the outer diameter of the braided suture, an inner diameter, and one or more openings therein, wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7; a surgical needle attached to the distal end of the braided suture; and a connector attached to the proximal end of the tube; comprising the steps of:

connecting the connector on the proximal end of the tube directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the tube;

introducing the suture/needle assembly into tissue surrounding the wound such that the one or more openings in the tube is at or in the proximity of the wound; and

closing the wound with the braided suture.

16. (Withdrawn) A method of administering a fluid to a wound that has been closed using a braided suture having an outer diameter; a tube coaxial with at least a portion of the braided suture, said tube having proximal and distal ends, an outer diameter that is less than the outer diameter of the braided suture,

an inner diameter, and one or more openings therein, wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7; and a connector attached to the proximal end of the tube; such that the one or more openings in the tube is at or in the proximity of the wound, comprising the steps of:

connecting the connector on the proximal end of the tube directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the tube; and

allowing the fluid to exit the one or more openings in the tube into at least a portion of the braided suture at or in the proximity of the wound.

17. (Withdrawn) A method of closing a wound and administering a fluid to a wound using a suture /needle assembly comprising a braided suture having proximal and distal ends and an outer diameter, a tube coaxial with at least a portion of the braided suture, said tube having proximal and distal ends, an outer diameter that is less than the outer diameter of the braided suture, an inner diameter, and one or more openings therein, wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7; a surgical needle attached to the distal end of the braided suture; and a connector attached to the proximal end of the tube; comprising the steps of:

introducing the suture/needle assembly into a tissue surrounding the wound such that the one or more openings in the tube is at or in the proximity of the wound; closing the wound with the braided suture;

connecting the connector on the proximal end of the tube directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the tube; and

allowing the fluid to exit the one or more openings of the tube into at least a portion of the braided suture at or in the proximity of the wound.

18. (Withdrawn) A method of closing a wound and administering a fluid to a wound using a suture /needle assembly comprising a braided suture having proximal and distal ends and an outer diameter, a tube coaxial with at least a portion of the braided suture, said tube having proximal and distal ends, an outer diameter that is less than the outer diameter of the braided suture, an inner diameter, and one or more openings therein, wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7; a surgical needle attached to the distal end of the braided suture; and a connector attached to the proximal end of the tube; comprising the steps of:

connecting the connector on the proximal end of the tube directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the tube;

allowing the fluid to exit the one or more openings of the tube into at least a portion of the braided suture;

introducing the suture/needle assembly into a tissue surrounding the wound such that the one or more openings in the tube is at or in the proximity of the wound; and

closing the wound with the braided suture.

19. (Withdrawn) A method of closing a wound using a suture/needle assembly comprising a first braided suture having an outer diameter, a coated fiber tow or braided suture coaxial with at least a portion of the first braided suture, said coated fiber tow or braided suture having proximal and distal ends, an outer diameter that is less than the outer diameter of the first braided suture, and one or more openings therein; a surgical needle attached to the distal end of the braided suture; and a connector attached to the proximal end of the tube; comprising the steps of:

connecting the connector on the proximal end of the coated fiber tow or braided suture directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the coated fiber tow or braided suture;

introducing the suture/needle assembly into tissue surrounding the wound such that the one or more openings in the coated fiber tow or braided suture is at or in the proximity of the wound; and

closing the wound with the first braided suture.

20. (Withdrawn) A method of administering a fluid to a wound that has been closed using a first braided suture having an outer diameter, a coated fiber tow or braided suture coaxial with at least a portion of the first braided suture, said

coated fiber tow or braided suture having proximal and distal ends, an outer diameter that is less than the outer diameter of the first braided suture, and one or more openings therein; and a connector attached to the proximal end of the coated fiber tow or braided suture; such that the one or more openings in the coated fiber tow or braided suture is at or in the proximity of the wound, comprising the steps of:

connecting the connector on the proximal end of the coated fiber tow or braided suture directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the coated fiber tow or braided suture; and

allowing the fluid to exit the one or more openings in the coated fiber tow or braided suture into at least a portion of the first braided suture at or in the proximity of the wound.

21. (Withdrawn) A method of closing a wound and administering a fluid to a wound using a suture /needle assembly comprising a first braided suture having proximal and distal ends and an outer diameter, a coated fiber tow or braided suture coaxial with at least a portion of the first braided suture, said coated fiber tow or braided suture having proximal and distal ends, an outer diameter that is less than the outer diameter of the first braided suture, and one or more openings therein; a surgical needle attached to the distal end of the first braided suture; and a connector attached to the proximal end of the coated fiber tow or braided suture; comprising the steps of:

introducing the suture/needle assembly into tissue surrounding the wound such that the one or more openings in the coated fiber tow or braided suture is at or in the proximity of the wound;

closing the wound with the first braided suture;

connecting the connector on the proximal end of the coated fiber tow or braided suture directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the coated fiber tow or braided suture; and

allowing the fluid to exit the one or more openings of the coated fiber tow or braided suture into at least a portion of the first braided suture at or in the proximity of the wound.

22. (Withdrawn) A method of closing a wound and administering a fluid to a wound using a suture /needle assembly comprising a first braided suture having proximal and distal ends and an outer diameter, a coated fiber tow or braided suture coaxial with at least a portion of the first braided suture, said coated fiber tow or braided suture having proximal and distal ends, an outer diameter that is less than the outer diameter of the first braided suture, and one or more openings therein; a surgical needle attached to the distal end of the first braided suture; and a connector attached to the proximal end of the coated fiber tow or braided suture; comprising the steps of:

connecting the connector on the proximal end of the coated fiber tow or braided suture directly or indirectly to a reservoir comprising the fluid;

exerting pressure on the fluid to force the fluid to enter into the connector and the coated fiber tow or braided suture;

allowing the fluid to exit the one or more openings of the coated fiber tow or braided suture into at least a portion of the first braided suture;

introducing the suture/needle assembly into tissue surrounding the wound such that the one or more openings in the coated fiber tow or braided suture is at or in the proximity of the wound; and

closing the wound with the first braided suture.

23. (Withdrawn) The method of claim 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22 where the reservoir is a syringe and pressure is exerted on the fluid via manual operation of the syringe.

Claim Support and Drawing Analysis

1. An active suture **{FIG. 1, element 10, p. 9, lines 16-22}** comprising

a braided suture **{FIG. 1, element 14}** having proximal and distal ends and an outer diameter **{FIG. 1, element 14, p. 9, lines 23-28}**, said braided suture having a plurality of interstices along at least a portion of its length **{FIG. 2, element 14, p. 10, lines 5-9}**; and

at least one passageway **{FIG. 1, element 12}** coaxial with at least a portion of the braided suture **{FIG. 1, elements 12 & 14, p. 9, lines 24-26}**, and having proximal and distal ends and a diameter that is less than the outer diameter of the braided suture **{FIG. 1, elements 12 & 14}** and having one or more openings therein **{FIG. 4b, elements 48}** so that said at least one passageway conducts fluid to said plurality of interstices of said braided suture **{p. 10, lines 5-9, p. 11, lines 11-16}**;

wherein the distal end **{FIG. 4b, element 46}** of the at least one passageway is disposed between the proximal and distal ends of the braided suture **{FIG. 4b, elements 12, 14 & 48}**.

2. An active suture **{FIG. 1, p. 9, lines 16-22}** comprising

a braided suture **{FIG. 1, element 14}** having an outer diameter **{FIG. 1, element 14, p. 9, lines 23-28}** said braided suture having a plurality of interstices along at least a portion of its length **{FIG. 2, element 14, p. 10, lines 5-9}**; and

a tube coaxial **{FIG. 1, element 12, p. 10, lines 18-20}** with at least a portion of the braided suture **{FIG. 1, elements 12 & 14, p. 9, lines 24-26}**, having an outer diameter that is less than the outer diameter of the braided suture and an inner diameter **{FIG. 1, elements 12 & 14}**, and having one or more openings therein so that said tube conducts fluid to said plurality of interstices of said braided suture **{p. 10, lines 5-9, p. 11, lines 11-16}**;

wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7 **{p. 16, line 27 to p. 28, line 3, p. 21, line 10 to p. 22, line 2}**.

4. (Original) The active suture of claim 1, where the at least one passageway **{FIG. 1, element 12}**is a lumen **{FIG. 2, element 12}** of a tube **{FIG. 2, element 24, p. 10, lines 18-20}**.

6. (Original) The active suture of claim 4, where the tube **{FIG. 2, element 24}** has one or more holes **{FIG. 4b, elements 48}** that connect the lumen **{FIG. 2, element 12}** to the outer surface of the tube **{FIGs. 2 & 4b, elements 12, 24 & 48}**.

Evidence

No further evidence is provided.

Related Cases

This case is related to pending U.S. Patent Application Serial No. 10/909,717. There are no related appeals or interferences.